REMARKS/ARGUMENTS

Claims 1-18 are pending with Claims 1 and 12 being the independent claims.

The Examiner is rejecting Claims 12-15 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,569,123 (Alchas, et al., hereinafter "Alchas"). In particular, the Examiner states:

> ...Alchas discloses an injection device comprising a: cartridge barrel (44), said barrel arranged to contain a stopper (28) and fluid therein and wherein said barrel has a second open end a second end having a radial flange adjacent to the second end; a needle cannula having a sharp distal end and a second open end, the fluid being in communication with said needle second end; a housing surrounding the barrel (12), said housing having a distal open end adjacent the needle and a proximate end having a flange receiving the radial flange of the barrel (16 is a flange and it receives within that end the flange of the barrel. Please note that the claim language does not require that the flanges contact each other); a shield releasably retained by the housing (20), said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Figs. 1-4); a driver (driver is combination of 26, 30 and 12 as they are all connected), said driver positioned partially within said housing (portion 12 is partially within the housing), said driver equipped with at least one deformable side arm sensing the end of the barrel (deformable side arms 14 detect the end of the barrel by means of detecting the end of 42), said driver slidingly located within said housing for moving the stopper forward (portion 12 is within the housing and is what moves the stopper forward); and a biasing spring (52), said biasing spring further adapted to bias the shield to automatically cover the needle after said driver detects the end of the barrel (Fig. 5). In reference to claims 13-17, see Figs. 1-5. (Office Action, pp. 2-3 of March 19, 2009).

Applicants respectfully disagree for the following reasons.

Firstly, the Examiner's citation of parts of Alchas is incorrect. In particular, the prefillable container 22 of Alchas comprises a reservoir 24. Item 44 is a stop portion of the container 22, ***not*** a cartridge barrel. Item 20 is ***not*** a housing but is the limiter structure 20 that is slidably engaged with the container 22. Item 12 is ***not*** a barrel but is the outer structure or sleeve of the Alchas injector; as such, "portion 12" cannot be contained within the housing" and cannot move any stopper forward (as suggested by the Examiner) since it is the outer surface of the

Alchas injector. Item 14 is the proximate end of the sleeve 12, *not* a deformable side arm.

Secondly, the prefillable intradermal injector of Alchas is designed and operates differently than the device of the present invention. For example, contrary to the Examiner's assertion that the Alchas injector comprises "a shield that is positioned primarily within the housing until release," the limiter 20 is *not* positioned primarily within the housing (i.e., sleeve 12) before injection occurs. In fact, as shown most clearly in Fig. 2, in the first position 39 (prior to injection), the majority of the limiter 20 is *external* of the sleeve 12 (compare the portion of the limiter 20 extending beyond the proximate end 14 of the sleeve 12 to that portion of the limiter 20 still within the sleeve 12).

Thirdly, the Examiner's assertion that the Alchas injector includes at least one deformable side arm that senses the end of the barrel, by means of detecting the end 42 is incorrect. There is no mechanism in Alchas that detects the end of the barrel (assumed to mean the distal end of the reservoir 24, or distal end of the container 22), nor that even detects the skin engaging surface 42. Rather, it is the release of the force from the activation flange 30 that causes the needle cannula 34 to be withdrawn into the limiter 20, as explained in Alchas:

> Referring to FIG. 5, subsequent to administering a intradermal injection, the limiter 20 is movable from the third position 47 to a fourth position 49, to enclose the needle cannula 34 inside the limiter 20. A spring 52 is optionally disposed inside the sleeve 12 and biases the limiter 20 outwardly of the sleeve 12. Preferably, the spring 52 is coiled around the prefillable container 22 and is compressed between the activation flange 30 and the limiter 20. **Upon releasing the force from the activation flange 30, the spring 52 forces the limiter 20 outwardly of the sleeve 12, which withdraws the needle cannula 34 back into the limiter 20, thereby moving the device from the third position 47 to the fourth position 49. When the limiter 20 has reached the fourth position, the catch 50 engages a slot 54 disposed in the sleeve 12 in a manner that locks the limiter 20 to prevent the limiter from being moved from the fourth position 49 back to the third position 47 in which the needle tip would be exposed.** (emphasis added, Alchas, col. 7, lines 34-52).

In addition, as can be seen from the above excerpt, the deformable member, namely, catch 50, engages a slot 54 in the sleeve 12 for locking the limiter 20 in place. Thus, Alchas teaches away from the present invention. In particular, in the present invention at least one deformable side arm senses the end of the barrel and *effects the shield deployment*; in contrast, in Alchas, it is when the limiter 20 reaches the fourth position that causes the deformable member, i.e., catch 50, to engage the slot 54. As a result, the catch 50 does not "detect" the end of any injector member. Thus, the present invention and the Alchas injector work just the opposite.

For all of these reasons, Applicants respectfully submit that Claim 12 is patentable over the art of record and respectfully requests that the §102(e) be withdrawn.

Claim 13 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 15 is dependent upon Claim 12 and is patentable for the same reasons.

Claim 16, although not addressed by the Examiner in the Office Action, is dependent upon Claim 15 and is patentable for the same reasons.

Claim 17, although not addressed by the Examiner in the Office Action, is dependent upon Claim 15 and is patentable for the same reasons.

The Examiner is rejecting Claims 1-11 and 18 under 35 U.S.C. §103(a) as being unpatentable over Alchas. In particular, the Examiner states:

> Claims 1-11, 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Alchas et al. (U.S. Patent No. 6,569,123). Alchas discloses an injection device comprising: a housing (19) having a proximate end and a distal end, the distal end having an opening therein; a cartridge barrel within the housing (22), the cartridge barrel having proximate and distal ends; a needle cannula fixed to the distal end of the cartridge barrel (34), or attachment means for fixing a needle cannula to the distal end; a stopper within the cartridge barrel (28); a driver coupled to the stopper (driver is combination of 26, 30

> and 12 as they are all connected); a shield coupled to the housing and slidable between a retracted and an extended position (20); shield driver means activatable to urge the shield from the retracted position to the extended position (52); and sensor means forming a portion of said driver (sensor means are 14) in slidable contact with an exterior surface of the shield, the sensor means arranged to detect an end profile of the barrel and to automatically trigger activation of the shield driver means upon detection (deformable side arms 14 detect the end of the barrel by means of detecting the end of 42). Alchas, however, does not disclose that the sensor means are in slidable contact with an exterior surface of said cartridge barrel. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Alchas by reversing the shield and the housing such that the sensor means were in sliding contact with the exterior of the cartridge barrel since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167. (Office Action, p. 4 of March 19, 2009).

Applicants respectfully disagree for the following reasons.

Firstly, as mentioned previously, the Examiner's citation of parts of Alchas is incorrect. There is no item "19" and the term "housing" is not even used in Alchas and the item 22 refers to the prefillable container; however, the outer structure of the Alchas injector is a sleeve 12. Item 28 is a stopper, *not* a barrel. Item 14 is the distal end of the sleeve 12, *not* sensor means, *nor* deformable side arms.

As mentioned previously with regard to Claims 12-15, the Alchas injector and the present invention are designed and operate differently. Thus, the Examiner's suggestion that it would have been obvious to one skilled in the art to "reverse the shield and the housing such that the sensor means were in sliding contact with the exterior of the cartridge barrel since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art" is using the present invention as a template to build the invention which is not permitted

under *In re Fritch*[1]. Not only would such a modification completely change the operation of the Alchas injector, it most probably would not work either. Firstly, it is not clear what part of the Alchas injector the Examiner considers "the housing" because the Examiner uses so many different reference numbers for that item and, as mentioned previously, the term "housing" is not even used in Alchas. Secondly, if what the Examiner means by "shield" in Alchas is the limiter 20, it is most unclear how the limiter could be placed outside the sleeve 12 (if this is what the Examiner considers "the housing"). Thirdly, the Examiner identifies the sensor means as 14 which, as also mentioned previously, is simply the distal end of the sleeve 12. It is again most unclear how reversing the shield (limiter 20?) and the housing (sleeve 12?) would result in the distal end 14 acting as a sensor means for sliding contact with the exterior of the cartridge barrel. Thus, Applicants respectfully submit that the Examiner has not set forth a prima facie case of obviousness and Applicants respectfully submit that the §103(a) rejection be withdrawn.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 3 is dependent upon Claim 2 and is patentable for the same reasons.

Claim 4 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 5 is dependent upon Claim 4 and is patentable for the same reasons.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 6 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 9 is dependent upon Claim 8 and is patentable for the same reasons.

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[1] *... the PTO may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious."* In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

Claim 10 is dependent upon Claim 8 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 18 is dependent upon Claim 1 and is patentable for the same reasons.

In view of all of the art previously considered and overcome by all of the foregoing responses to Office Actions, including the present Office Action, Applicants respectfully submit that Claims 1-18 are now in condition for allowance and that this application be moved to allowance as soon as possible.

Respectfully submitted,

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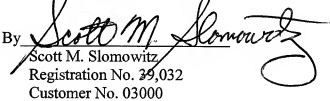
By 
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